MINERAL MATTESCREEN SPF 40- titanium dioxide, zinc oxide cream Taylor James Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mineral Mattescreen SPF 40

Active Ingredients Purpose

Titanium Dioxide 1.3% Sunscreen

Zinc Oxide 17.4% Sunscreen

Uses

- Helps Prevent Sunburn
- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.
- **Keep out of reach of children.** If product is swallowed, get medical help or contact a poison Control Center right away
- Stop use and ask a doctor if rash occurs.

Warnings

- · For external use only
- **Do not use** on damaged or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.

Directions

- Apply generously and evenly 15 minutes before sun exposure
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating
- Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a Broad-Spectrum SPF value of 15 or higher and other sunprotection measures including: limit your time in the sun, especially from 10a.m. 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: ask a doctor.

Inactive Ingredients

Dimethicone, Dimethicone Copolymer, Caprylic/Capric Triglyceride, Methyl Dihydroabietate, Polyhydroxystearic Acid, C9-12 Alkane, Glycerin, Iron Oxides (CI 77492), Ethylhexylglycerin, Water (Aqua), Coco-Caprylate/Caprate, Silica, Stearic Acid, Iron Oxides (CI 77491), Iron Oxides (CI 77499), Hedychium Coronarium Root Extract, Lactobacillus/Arundinaria Gigantea Leaf Ferment Filtrate, Leuconostoc/Radish Root Ferment Filtrate, Titanium Dioxide (CI 77891)

Mineral Mattescreen SPF 40

1.5 fl. oz./45 ml	

MINERAL MATTESCREEN SPF 40				
titanium dioxide, zinc oxide cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-281	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.3 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.4 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)			
FERRIC OXIDE YELLOW (UNII: EX43802MRT)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)			
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-281-01	5 mL in 1 TUBE; Type 0: Not a Combination Product	05/18/2021	
2	NDC:75936-281-02	10 mL in 1 TUBE; Type 0: Not a Combination Product	05/18/2021	
3	NDC:75936-281-03	45 mL in 1 CARTON; Type 0: Not a Combination Product	05/18/2021	
4	NDC:75936-281-04	20 mL in 1 TUBE; Type 0: Not a Combination Product	09/02/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/18/2021	

Labeler - Taylor James Ltd. (033381850)

Registrant - Englewood Lab, Inc. (080987545)

Establishment				
Name	Address	ID/FEI	Business Operations	
Englewood Lab, Inc.		080987545	manufacture(75936-281)	

Revised: 8/2021 Taylor James Ltd.